K122760

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DEC 7 2012

510(k) Summary of Safety and Effectiveness

Date Prepared: **September 10, 2012**

Applicant: Medtronic, Inc.
7611 Northland Drive
Minneapolis, MN 55428
Establish Registration Number: 2184009

Contact Person: Julia A. Nelson
Principal Regulatory Affairs Specialist
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Trade Name: Affinity® AF100 Arterial Filter with Balance® Biosurface
Common Name: Arterial Filter
Classification Name: Cardiopulmonary bypass arterial line blood filter
Classification: Class II, 21 CFR 870.4260

Product Code: DTM

Name of Predicate Device: Affinity Arterial Filter with Trillium (20µm) Model 353T (K033468)

Device Description:

The AF100 is designed to filter from the circuit microemboli larger than the specified micron size for periods up to six hours during cardiopulmonary bypass surgery.

The AF100 with Balance Biosurface (BB851) is coated with a nonleaching biocompatible surface to reduce platelet activation and adhesion and preserve platelet function. The device is single-use, nontoxic, nonpyrogenic, supplied STERILE in individual packaging. The AF100 is sterilized by ethylene oxide.

Intended Use:

The AF100 is indicated for use in cardiopulmonary bypass procedures up to 6 hours in duration for the removal of particulate and gaseous microemboli.

Contraindications:

Do not use this device for any purpose other than indicated.

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Comparison to Predicate Devices:

A comparison of Affinity AF100®Arterial Filter with Balance® Biosurface to the predicate device indicates the following similarities:

- Same intended use
- Same technological characteristics
- Same operating principle
- Same design features
- Similar materials with the exception of the housing material of the AF100 device. The AF100 housing is made of a Bisphenol A-free (BPA-free) copolyester material, which differs from the polycarbonate material used in the predicate device.
- Same shelf life

Summary of Performance Data

Pre-clinical bench testing was used to verify the performance characteristics of this device. Clinical testing was not required to establish substantial equivalence with the predicate devices.

The following performance tests were conducted:

- Blood Damage Testing
- Pressure Drop
- Structural Integrity
- Air Handling Capabilities
- Filtration Efficiency
- Burst Pressure
- Coating Integrity
- Priming Volume
- Particulate Shedding

Conclusion:

The data included in this submission is sufficient to provide reasonable assurance of the safety and effectiveness of the device and the Affinity® AF100 Arterial Filter with Balance® Biosurface is substantially equivalent to the legally marketed predicate device, Affinity Arterial Filter with Trillium (20μm) Model 353T (K033468).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

DEC 7 2012

Medtronic Cardiovascular
Julia A. Nelson, Principal Regulatory Affairs Specialist
8200 Coral Street NE
Mailstop MVS83
Mounds View, MN 551112

Re: K122760
Trade/Device Name: Affinity AF100 Arterial Filter with Balance Biosurface
Regulation Number: 21 CFR 870.4260
Regulation Name: Cardiopulmonary Bypass Oxygenator
Regulatory Class: Class II
Product Code: DTM
Dated: September 10, 2012
Received: September 12, 2012

Dear Ms. Nelson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh for

Bram D. Zuckerman, M.D.
Division Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Indications for Use Statement

510(k) Number (if known): K122760

Device Name:

Affinity® AF100 with Balance® Biosurface

Indications for Use:

The AF100 is indicated for use in cardiopulmonary bypass procedures up to 6 hours in duration for the removal of particulate and gaseous microemboli.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K122760